Information and Instructions for

Patients Considering *an*

AMS 700® with MS Pump® Series

Inflatable Penile Prostheses

English

AMS®
an endo health solution

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1 General warnings and cautions.

1.1 How safe are silicone elastomer prostheses?

The AMS 700® with MS Pump® Penile Prostheses Product Line devices are made of solid silicone elastomers (a type of rubber). Penile prostheses, or solid silicone elastomers, do not contain silicone gels. Silicone elastomers have been commonly used in many different types of biomedical devices for over 40 years.

Solid silicone elastomers are also used to compare against when a new material is being considered for use in a biomedical device. The new material is tested to see if it is as biocompatible (causes as few problems in living tissue) as silicone elastomers.

Scientific literature has included reports of adverse events in some patients with implantable silicone devices. These adverse events indicate allergic-like reactions or autoimmune-like symptoms. (In an autoimmune reaction, the body's own immune cells may attack some or many of the body's own tissues by mistake.) However, even though these reactions or symptoms were seen in some patients, there has been no proof that the silicone elastomer caused them.

Silicone elastomer may sometimes lose tiny particles off its surface after it has been implanted. Sometimes these particles migrate (move) to lymph nodes in other parts of the body where the particles then stay. (Your lymph nodes are a normal part of your body's defense system against infection.) Medical journals, however, have indicated that particle migration has not resulted in any adverse effects to a patient's health.[1,2]

Fluorosilicone (a silicone fluid) is also used as a lubricant between internal silicone elastomer and fabric layers in the cylinder to reduce wear. Silicone fluids have a large history of use in medical devices, such as lubricating hypodermic syringes.

[1] Barrett DM, O'Sullivan DC, Malizia AA, Reiman HM and Abell-Aleff PC. "Particle Shedding and Migration from Silicone Genitourinary Prosthetic Devices," *J. Urol. 146:* 319-322. (1991)
[2] Reinberg Y, *J. Urol. 750:* 694-696. (1993)

1.2 Will my prosthesis have to be replaced?

It is not possible to predict how long an implanted penile prosthesis will function in a particular patient. As with any biomedical device, penile prostheses are subject to wear and eventual failure over time, and therefore should not be considered to be lifetime implants. Other causes can lead to malfunctions of the prosthesis which occur more quickly. Discuss any changes you notice in the function of the prosthesis with your doctor.

Product wear or other mechanical problems, such as unintended inflation or deflation, or difficulty or inability to inflate or deflate may lead to additional surgery to remove or replace the device.

Because it is not possible to tell how long an implanted penile prosthesis will function in a particular patient, AMS has collected information on three sets of data on device removals and revisions to help you understand product performance over time.

The first data set comes from a clinical trial conducted for this penile prosthesis. This data shows that approximately 84% of patients receiving an implant did not require additional surgery (to remove or replace the prosthesis) for 5 years after the original surgical implant.

The second set of data comes from Patient Information Forms (PIFs) submitted to AMS by doctors after surgical procedures for penile prostheses requiring replacement of parts. This data indicates that approximately 89% of patients receiving an implant did not require any additional surgery (to remove or replace the prosthesis) for 5 years after the surgical implant.

The third set of data comes directly from physician implant records. These records contain information on each surgery for any reason performed by a doctor after an original implant. This data set indicates that approximately 82% of patients did not require any additional surgery (to remove or replace the prosthesis for any reason) for 5 years after the original implant.

1.3 Need for manual dexterity

The AMS 700 with MS Pump prostheses require some manual dexterity to inflate and deflate.

1.4 Possibility of malfunction

The possibility of leakage, blockage, or device malfunction exists.

1.5 Possibility of changes in the penis or scrotum

Implantation of a penile prosthesis may cause the penis to become shorter, curve, or be scarred. Scrotal deformity (pump bulge in the scrotum) may also occur.

1.6 Destruction of any latent natural erection

Implanting a penile prosthesis is likely to damage or destroy any remaining natural ability to have an erection.

1.7 Different erection

Your erection with the prosthesis may be different from your original, natural erection. Differences may include a shorter penis, less firmness, less width, and reduced sensation in the penis. Also, because the prosthesis will not extend to the tip of your penis (the glans), this part of your penis may be floppy.

1.8 Less softness when deflated

When your prosthesis is deflated, your penis may not be as soft (flaccid) as it was naturally.

1.9 Possibility of infection

Contact your doctor immediately if there is redness, swelling, and/or heat around the incision area or drainage from the incision. This may indicate an infection.

1.10 Delay intercourse until your doctor gives the OK

If you attempt intercourse before your incision has healed completely, you risk the possibility of infection, pain, or surgical complication.

1.11 Erosion

Contact your doctor immediately if there is thinning of skin or tissue over the prosthesis. This may indicate erosion. Failure to treat erosion can make it worse and lead to infection and loss of tissue.

1.12 Pain

Contact your doctor if you have pain that is very severe or if it lasts longer than expected. Such pain may be a symptom of a medical complication or mechanical device malfunction.

1.13 Migration

Contact your doctor if the surface of any part of your device is visible through your skin or if you cannot locate the MS pump in your scrotum. These symptoms may indicate that a part of your device may have moved within your body or may be moving to the outside of your body.

1.14 Allergic Reaction

If you have a AMS 700 with MS Pump with InhibiZone® and exhibit symptoms of an allergic reaction, such as a rash, hives or difficulty breathing, contact your doctor immediately. Because of this slight risk of allergic reaction, you should be sure and inform your doctor about any allergies you may have to antibiotics *prior* to your surgery.

2 What is impotence?

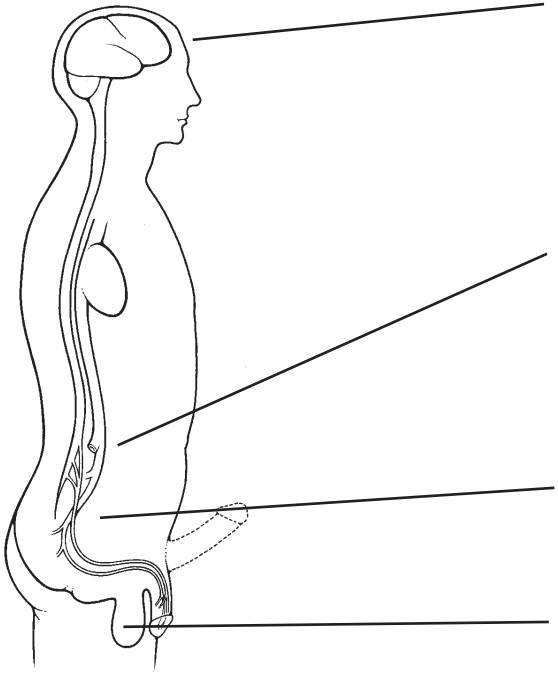
Impotence (also known as male erectile dysfunction) is the inability to maintain an erection that is firm enough or that lasts long enough to have successful intercourse.

Impotence:
- Is frustrating
- Has physical or psychological causes
- Is common

Impotence:
- Is not premature ejaculation
- Is not low sex drive
- Is not the need for manual or oral stimulation to get an erection
- Is not caused by too much sex
- Is not caused by masturbation when you were younger
- Is not connected to infertility
- Is not “normal” at any age

2.1 How does an erection occur?

For an erection to occur, several parts of the body must work together. The brain sends messages to control the nerves, hormone levels, blood flow and muscles that cause an erection. If anything interferes with one or more of these messages, or if any part of the system doesn't function correctly, an erection wil not occur.



The brain controls all sexual functions, from being aroused to starting and controlling the psychological, hormonal, nerve, and blood flow changes that lead to an erection.

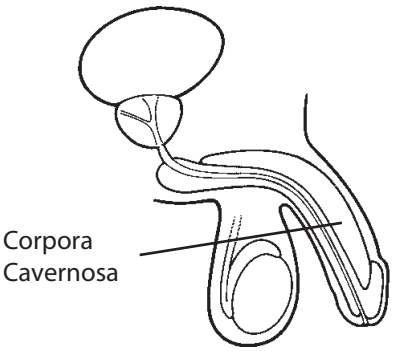
Arteries deliver the extra blood to the penis that causes it to stiffen. Veins then drain the blood out of the penis after intercourse.

Nerve impulses relay signals of arousal and sensation to and from the penis.

Hormones, including testosterone, control the male sex drive. Testosterone is secreted by the testicles.

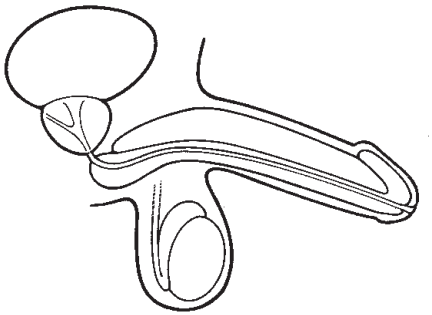
The flaccid penis

The shaft of the penis contains the corpora cavernosa, two channels which run the full length of the penis and into the pelvis. These channels are rich in special blood vessels which contain relatively little blood when the penis is flaccid (soft, relaxed, not enlarged). Without sexual stimulation, the penis remains flaccid.



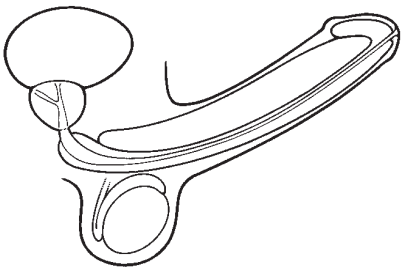
The tumescent penis

When the brain is sexually aroused, it stimulates the nervous system to enlarge the blood vessels in the corpora cavernosa, making room for extra blood. The corpora cavernosa absorb arterial blood flow like a sponge. At this point the penis is swollen, but not yet rigid (hard) enough for intercourse.



The erect penis

As the corpora cavernosa continue to absorb blood, the swelling puts pressure on the veins in the penis. This traps the blood in the corpora cavernosa, making the penis rigid (hard).



2.2 Impotence is common

Most men occasionally have difficulty getting an erection. However, about one in ten men are afflicted by chronic (continuing) impotence.

Impotence can be devastating to those affected by it. Unfortunately, it can also be very difficult to talk about. But the first step is to seek professional help. If your doctor regularly treats impotence problems, you can be sure that any question you ask will be one he has heard before from other patients.

2.3 Impotence is treatable

In more than half of all impotence cases the cause is physical–the result of diabetes, blocked arteries, a hormone problem, or other causes. In other cases, the cause could be psychological–the result of stress or depression. And in many cases, physical causes can produce psychological side effects.

Diagnosing the cause is the first step before recommending a treatment. Your doctor will require a thorough history, physical examination, and laboratory tests to determine whether the impotence has a physical or psychological cause.

The good news is that there are treatments available. And there is usually more than one option. Choices may range from sex counseling or marriage counseling, to medical and surgical treatments. Your doctor can determine which treatment alternative is appropriate for you. Most impotence problems can be treated successfully.

3 Causes of Impotence.

3.1 Psychological causes

Depression can cause a lack of energy and a reduced sex drive. This may result in an occasional inability to get an erection. If this happens, you may become even more depressed. This can lead to impotence. The first step is to treat the depression.

Stress can also result in an occasional inability to get an erection. Stress can be caused by your job, marital, financial, or other situation. Like depression, this inability to have an erection adds to the stress and can lead to impotence.

Performance anxiety (fear that you will fail if you try to have intercourse) happens to most men once in a while. If it keeps happening it can lead to the inability to have an erection and, ultimately, impotence.

Misinformation about sexuality and about how men should or shouldn't be able to "perform" at a certain age can lead to anxiety and stress, which can lead to impotence.

To treat a psychological cause, your doctor may recommend that you seek treatment from a qualified psychologist, psychiatrist, sex therapist, or marriage counselor. Counseling can often resolve the psychological problem causing impotence or be part of the recommended treatment. You and your partner may wish to go through counseling together.

Even if the problem is physical, there may be psychological side effects. Therefore, counseling may also be part of the recommended treatment for a physical problem.

3.2 Physical causes

Diabetes can cause damage to the nerves or blood vessels that control the flow of blood to the penis. In some cases, keeping your diet and blood sugar under control can help. But permanent damage to these nerves and vessels may result in chronic (continuing) impotence.

Cardiovascular problems, such as hardening of the arteries, can decrease the blood flowing into the penis. This makes it difficult for you to get or keep an erection. In other cases, the veins that keep the blood in the penis during an erection are damaged. If this happens, you cannot keep the erection long enough for sexual intercourse. Impotence can also occur if the nerves that control this flow of blood to the penis are damaged by lack of blood.

Trauma (injury) or **pelvic surgery**, including cancer surgery in the prostate, bladder, colon or rectal area, can cause impotence. In cancer surgery, the surgeon's most important goal is to remove all of the cancer. Nerves and blood vessels that control erections may be near the cancerous tissue. Sometimes these are damaged in an effort to remove the cancer.

Neurological disorders such as spinal cord injuries can cause impotence. The spinal cord is the relay center for nerve impulses, brain messages and blood flow. When the spinal cord is damaged in certain locations, messages can't get through to the nerves of the penis, causing impotence.

Medications may cause impotence by interfering with the nerve impulses or blood flow to the penis. These medications include some prescriptions for high blood pressure, depression and a number of other conditions. Sometimes a change in the medication or the dosage will decrease the risk of impotence.

CAUTION: Medications should never be changed without the doctor's permission.

Alcoholism changes hormone levels and can lead to permanent nerve damage, causing impotence. This type of impotence may be reversible, depending on the severity of the nerve damage.

Hormone problems are rarely the cause of impotence, but certain diseases can change the balance of hormones which control erections. Kidney failure and liver disease are among these conditions.

4 Am I impotent?

If, after reading this, you are still questioning whether or not you are impotent and what the cause may be, the following questions may indicate whether you should consult a urologist, a doctor who specializes in treating problems associated with the urinary tract. In general, if you answer "yes" to any of the first six questions, you should see a urologist who specializes in the treatment of impotence.

If your current doctor does not regularly treat impotence problems, you might ask for a referral to a urologist who specializes in the diagnosis and treatment of impotence.

When you see the urologist, share the answers from the following self-test. This information will be valuable to the doctor as he or she determines a diagnosis.

Most importantly, you should know that continuing impotence is not a problem that you should have to live with, or that will just go away. It's important to make a medical appointment as soon as the problem becomes apparent. It is important so that you can help avoid the psychological problems that may make it worse. Remember that impotence can be treated in almost every case.

4.1 Impotence self-test**

Current Sexual Performance

1. Have you had any difficulty recently in achieving erections?
2. Does this problem occur at least three out of every four times that you attempt intercourse?

Sexual Performance Trends

3. Have you been having difficulty for longer than one month in achieving erections regularly?
4. Are morning and spontaneous erections becoming less common?
5. Does it take much longer to achieve an erection than in the past?
6. Has it become more difficult to have intercourse in certain sexual positions?

Medical History

7. Have you ever been told you have any form of heart disease, especially hardening of the arteries, peripheral arterial disease (PAD), or hypertension?
8. Have you ever had an operation for heart disease or some other cardiovascular problem?
9. Have you ever been told you have an elevated cholesterol level?
10. Do you ever experience serious pain in the legs when walking?
11. Are you taking drugs on a prescription basis for any other problem?*
12. Do you have any known glandular disorder, especially diabetes?
13. Do you have any neurological disorder, such as multiple sclerosis or epilepsy?

14. Have you ever had major surgery in the pelvic area, especially surgery involving the prostate gland or colon?

15. Have you ever had an injury involving the pelvic area, back, spinal cord, or head?

16. Have you ever been treated with radiation therapy for a problem in the pelvic area?

17. Have you ever had an episode of priapism (an erection which lasts for longer than usual and becomes painful)?

Lifestyle

18. Do you now smoke or did you once smoke for a long period of time?

19. Are you a heavy drinker or a diagnosed alcoholic?

20. Have you used illegal drugs, especially cocaine?

21. Are you a frequent user of drugs you can buy at the drugstore without a doctor's prescription?

22. Are you excessively overweight?

If it is determined that you are impotent, and that your impotence is caused by a physical problem, your doctor can offer several options for treatment. These may include hormone therapy, injections, vacuum devices, penile implants, or vascular surgery.

CAUTION: Medications should never be changed without the doctor's permission.

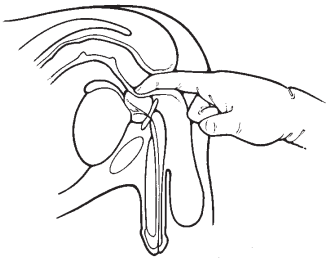
** Self-test questions are reprinted and edited with permission from Love Again, Live Again by Steven Morganstern, MD, and Allen Abrahams, PhD.

5 What to expect at your examination.

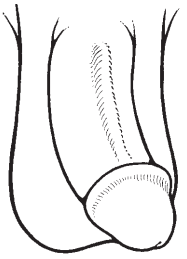
5.1 Physical examination

Your doctor will ask you several questions in order to understand when and under what circumstances you experience signs of impotence. Then your doctor will give you a complete physical exam. This exam is to determine if the blood vessels, nerves, and tissues of your penis are working normally.

Your doctor may begin by feeling for the pulse in your penis and surrounding pelvic area. This will give an indication if the blood supply to your penis is adequate.



Your doctor must also perform a rectal examination to check for prostatitis (a swollen prostate gland). Problems with your prostate can decrease blood flow and feeling in the penis. Prostatitis can also make intercourse uncomfortable.



Your doctor will also check for physical abnormalities such as Peyronie's disease (a curved and painful erection caused by scar tissue within the penis). He will also check your history for previous injuries or surgery in the pelvic area which may have caused nerve damage.

5.2 Tests you may be asked to take

To confirm your diagnosis, other tests can detect hormonal abnormalities, determine blood flow problems, and may help to rule out psychological problems.

Blood tests and urine analysis

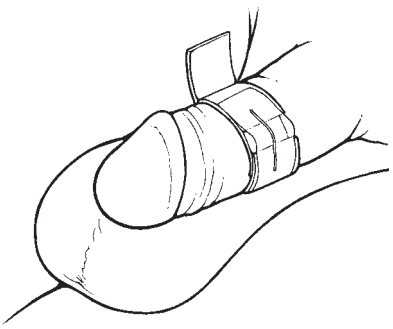
These tests are used to measure your hormone levels, cholesterol, and triglycerides (to detect hardening of the arteries), and liver and kidney function. To detect diabetes mellitus, a blood glucose test may also be requested.

Penile blood flow studies

Additional tests may be done to see how effectively blood flows into the penis. One test involves an injection with a drug that increases the blood flow to the penis directly, without stimulating the nerves in the penis. If the blood vessels of your penis are healthy, this injection will produce an erection.

Sleep monitoring

Most men experience at least 3 to 4 erections each night when they are dreaming. If you don't have nighttime erections, perhaps the nerve or blood supply to your penis is inadequate for erections. Your doctor may ask you to measure nighttime erections at home with a simple test that he or she will provide.



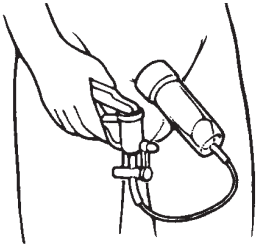
6 Treatment options for physical causes of impotence.

Depending on your diagnosis, your recommended treatment may be medical or surgical. Medical treatments range from simply changing your prescription drugs, to hormone replacement therapy, antidepressant therapy, and devices or self-injection therapy to produce erections. Surgical treatments include vascular surgery or implants. Your doctor will discuss options that may be appropriate in treating your impotence, as well as the risks and benefits of each option.

6.1 Medication

Changing prescription medications or their dosages may change the side effects, which may be causing your impotence. Hormone replacement therapy may be recommended if you have a hormone deficiency. Antidepressant drugs may be the first course of treatment if you've been diagnosed with severe clinical depression. Drugs that increase the flow of blood to the penis to help cause an erection are also available.

6.2 Vacuum erection devices



These devices are placed around the outside of the penis and draw blood into the penis by creating a vacuum. Then you or your partner place a constriction band (rubber band) around the base of the penis to keep the blood inside the penis until sexual intercourse is completed.

6.3 Injections

Injecting medication directly into the penis prior to intercourse can also produce an erection. If you and your doctor choose this option, you will be taught how to administer the injections yourself.

6.4 Vascular surgery

For a few men, vascular surgery may be indicated to improve blood flow into the penis. Leaking veins may also be surgically repaired. In cases where arterial blockage is reducing blood flow to the penis, an arterial bypass around the blockage may be recommended.

6.5 Surgical implants

Penile implants, or prostheses, may be a choice that lasts longer for a number of impotent men, especially those who've tried psychological and other medical treatments without success. Implants have helped over 300,000 return to an active sex life. Many studies show most patients and their partners are highly satisfied with the results.

Implants are concealed entirely within the body. They require manipulation by you or your partner before intercourse to make the penis firm enough for sexual intercourse. Manipulation is also needed afterwards to return the implant to a relaxed state (make it flaccid).

There are several types of implants to choose from. Differences include manner of operation, naturalness of the erection, and the number of components implanted. In choosing a penile prosthesis you should consider the manual dexterity that is needed to operate each type of device. The best choice of penile prosthesis for you will depend upon your medical condition, your lifestyle and, possibly, the cost of each prosthesis.

Before deciding on a penile prosthesis, you should consult with your doctor about the physical, psychological, cosmetic, and functional outcome of the implantation surgery. You should be sure that you understand the risks and benefits of the surgery.

There are certain instances when you and your physician may decide that a surgical implant is not an appropriate choice for you if:

- the risks associated with surgery are too high because of your medical condition
- your medical history includes previous surgery which make an implant impossible
- you are satisfied with one of the less invasive treatment options discussed in section 6
- you choose not to be implanted with a silicone elastomer device
- you want to preserve the internal physical structure of your penis in case someday you may again experience a normal erection

In addition to discussions with your doctor, you may want to discuss the various options with your partner.

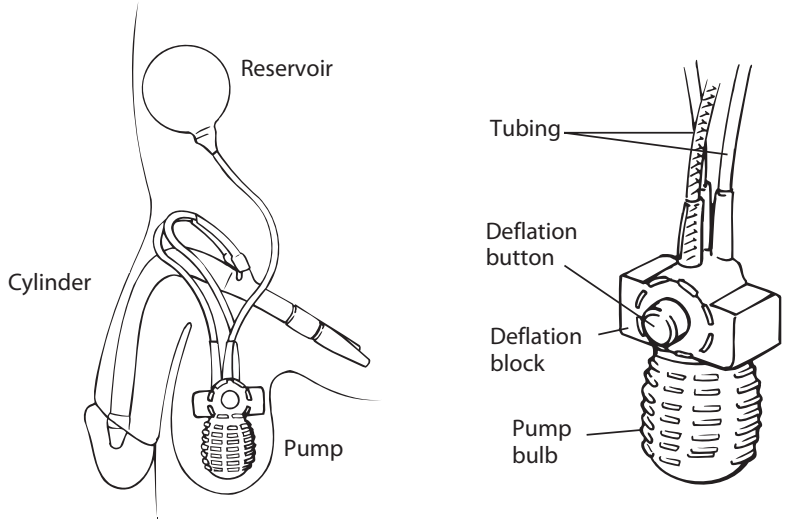
7 Description of the AMS Penile Prosthesis Product Line

The AMS 700 with MS Pump prostheses consist of four parts which are connected by tubing: a reservoir, two cylinders, and the MS pump.

The **reservoir** is implanted in the lower abdomen, under the muscle layer, and is filled with sterile saline solution.

The two **cylinders** are inserted side by side into the corpora cavernosa of the penis.

The **pump** is placed in the scrotum. The lower, rounded part of the pump is the **pump bulb**. The upper part of the pump that is rectangular in shape is the **deflation block**. The parts of the pump are marked in the figure below. Squeezing the deflation button starts to deflate the cylinders. Squeeze the deflation button for about 4 seconds to completely deflate the cylinders.



There are three models of inflatable penile prostheses in the AMS 700 product line. Your doctor will choose the right model for you based upon your anatomy and medical history.

AMS 700 LGX® with MS Pump® Penile Prosthesis

The 700 LGX cylinders are designed to expand in both length and width (girth). The amount of cylinder lengthening which actually occurs with use depends on how much the tissue in your penis allows them to lengthen and whether you are able to completely inflate the cylinders. This means that even if the cylinders inside your penis get longer when you fill them with fluid, they cannot make your penis any longer than it is now.

CAUTION: Implantation of a penile prosthesis may cause the penis to become shorter, curve, or become scarred.

AMS 700 CX® with MS Pump® Penile Prosthesis

The cylinders expand in width (girth) only and, like all AMS cylinders, they have been designed to resist uneven inflation.

AMS 700 CXR® with MS Pump® Penile Prosthesis

The 700 CXR cylinders have the same feature as the 700 CX. However, these cylinders are more appropriate for patients whose anatomy requires shorter, narrower cylinders.

8 What to expect during and after implant surgery.

Implantation of a penile prosthesis involves a surgical procedure usually lasting from 30 minutes to 2 hours. The length of your hospital stay depends on your physical condition and the type of prosthesis chosen. You will be able to return to work and everyday activities at the discretion or direction of your physician. (Everyday activities include any type of activity you were able to perform before your implant surgery, for example, exercise, working, bathing.)

8.1 The surgical method

Your doctor should be able to give you a thorough explanation of what will happen during the surgery and the rest of your hospital stay. In general, the procedure begins with some preoperative tests, which may include blood tests, urine analysis, and delivery of antibiotics.

Depending on your physical condition and your doctor's preference, you will either be given a local anesthetic (it numbs only the area where the surgery occurs) or a general anesthesia (which puts you to sleep for the surgery). If you are to be given a general anesthetic, you will be asked to abstain from food or drink for 12 hours before surgery.
There are two kinds of incisions. Your doctor will choose the right one for you:

- **penoscrotal** (between your penis and scrotum)
- **infrapubic** (in the lower abdomen above the penis)

Penoscrotal

If your doctor chooses the penoscrotal approach, an incision will be made through the skin between your penis and scrotum. Your doctor will usually implant the cylinders, the MS pump and the reservoir through this one incision. Occasionally, the doctor will also make a small incision in the lower abdominal area to place the reservoir.

To implant the cylinders, your doctor will first dilate (widen) the corpora cavernosa (the two channels in the shaft of your penis which fill with blood when you get a natural erection). Then your doctor will measure this area to choose which size cylinder will best fit your anatomy.

After the cylinders are in place, your doctor will make a space in your scrotum in which to place the pump. He will place the pump so that it is easy for you to reach.

Next, your doctor will make a space for the reservoir in your abdomen and connect all the tubing.

Finally, before closing the incision in your skin, your doctor will inflate and deflate the prosthesis to make sure it is working properly.

Infrapubic

An incision will be made in the skin of your lower abdomen. Your doctor will implant the cylinders, pump, and reservoir through this one incision. The same steps used in the penoscrotal approach described above are used here.

Penoscrotal and Infrapubic

After surgery is completed, your doctor will usually deflate the prosthesis and tape your penis against your abdomen. Your doctor may insert a catheter (a hollow tube) into your penis to drain your bladder. The catheter will be removed before you leave the hospital.

Your doctor may also insert a tube into your abdomen to drain excess fluid (blood) from the incision site. This will also be removed usually within 12 to 24 hours after surgery (or when drainage stops).

8.2 After your surgery

After you leave the hospital, you will be encouraged to avoid wearing tight-fitting underwear. This helps to prevent any curvature in your penis that could occur during healing. Likewise, after voiding you should carefully retape your penis to the abdomen in the same position (straight) that it was in prior to untaping.

Many doctors recommend that you wait four to six weeks before having intercourse. This time allows your incision site to heal.

CAUTION: If you attempt intercourse before the incision has healed completely, you risk the possibility of infection, pain, or surgical complications.

You will probably have an appointment with your doctor during this time to be sure you are healing properly. Be sure to discuss these possibilities with your doctor and ask how long after your surgery you should wait before having intercourse.

You may experience pain at the operative site(s) during the early time after surgery and when you first use your prosthesis. In most cases the pain goes away within a few weeks of surgery; however, cases of chronic (continuing) pain have been reported.

Recovery times vary from patient to patient. You will be able to return to work and everyday activities at the discretion or direction of your physician. (Everyday activities include any type of activity you were able to perform preoperatively, for example, exercise, working, bathing.) Your doctor will also talk to you about when you will be able to use your device.

After your doctor says you can begin using the device, follow the operating instructions given in Section 9.

CAUTION: Use of injection therapy into the penis (i.e., injection of medications for impotence) can damage the penile prosthesis. Do not use injection therapy after you receive your implant.

You will also have several postoperative visits, and annual or semi-annual follow-up visits with your doctor after the surgery. During this recovery time and after, take care to avoid trauma to the pelvic or abdominal area. Always keep in mind that you have had a surgical implant and choose your activities wisely. Examples of such trauma may include a seat belt jolt from a car accident, being tackled in contact sports, or slipping and falling on ice. Trauma may damage the prosthesis or surrounding tissues.

CAUTION: Take precautions to avoid trauma to your pelvic and abdominal areas such as might occur during contact sports, slipping on ice, etc.

8.3 Problems that may develop

Implant surgery carries the same types of risks that every surgical procedure involves, including that of infection and those associated with anesthesia. In addition, the outcome of your implant surgery may be unsuccessful. For example, the device may fail to function as intended. If this happens, you may need additional surgery to remove or replace the prosthesis. If the prosthesis must be removed, reimplantation of a new prosthesis may be complicated by the amount of time between the two surgeries. Discuss these possibilities with your doctor.

Infection

Infection can happen after any kind of surgery. Your doctor will try to lower your risk by giving you antibiotics before and after your operation and by flushing (washing out) the surgical site with antibiotics during surgery. Some conditions increase the risk of getting an infection:

- diabetes
- a spinal cord injury
- open sores
- an existing skin infection near the incision site
- an existing urinary tract infection

Information about the effectiveness of the antibiotic treatment, referred to as InhibiZone® (IZ), in preventing infections comes from Patient Information Forms (PIFs), which are records submitted to AMS by doctors after surgical procedures to implant penile prostheses or replace parts of previously implanted devices. More than 43,000 surgeries have been recorded in the AMS PIF database during the period since IZ was introduced over 6 years ago. During this period, approximately 1.2% of patients implanted with an IZ-treated prosthesis required a second surgery to replace or remove the prosthesis because of infection. This rate is compared to patients implanted with prostheses that were not treated with IZ (non-IZ), where approximately 2.5% of patients required a second surgery due to infection.

WARNING: Contact your doctor immediately if you notice any redness, swelling, and/or heat around the incision area or drainage from the incision. These symptoms may indicate an infection.

If you get an infection that cannot be treated successfully with antibiotics, your doctor may have to remove the prosthesis. It may not be possible to implant a new one.

Also, if your prosthesis must be removed because of infection, that infection may leave scars inside your penis. This may also make implanting a new prosthesis difficult.

Allergic Reaction

Allergic reactions may occur if you have sensitivity to the antibiotics that were used during the penile prosthesis implantation procedure or, if you are implanted with the AMS 700 series with MS Pump with InhibiZone®*, to the antibiotics impregnated into the penile prosthesis.

****WARNING: Contact your doctor immediately if you notice signs of an allergic reaction such as rash, hives or difficulty breathing.***

Erosion

Erosion is when the tissue next to any part of the device is "worn away". Conditions that can cause erosion include:

- infection
- pressure on the tissue, cutting off the blood supply
- improper sizing
- tissue damage
- misplacement of the cylinders, reservoir, or MS pump

Erosion involving the cylinders most often involves:

- the glans (the tip of the penis)
- the urethra (the tube inside the penis that carries urine out of the body)
- the skin of the penis

The pump may erode through the skin of the scrotum.

The reservoir can erode into the bladder or bowel.

Symptoms of erosion into the scrotum or penis may include, after having been symptom free, pain, redness of skin, tenderness over the involved part, changes in skin texture, drainage, and/or being able to see the prosthesis through the skin. Erosion into the bladder may result in pain, tenderness in bladder area, a change in your ability to urinate or a change in the color of urine. Less than 1.5% of patients in the clinical trial experienced erosion of any part of the device.

WARNING: Contact your doctor immediately if you notice any pain, tenderness over the involved part, change in skin texture, drainage, or if you can see the prosthesis through your skin. These symptoms may indicate erosion. Failure to treat the erosion can make it worse and lead to infection and loss of tissue.

Your doctor must evaluate any possible erosion. Sometimes the tissue can be repaired and only part of the prosthesis replaced. Other times the entire device must be removed.

Trauma

Trauma (injury) to the hip or stomach area can cause damage to either the device or the surrounding tissue in your penis, scrotum or abdomen. This can cause the device to malfunction and could require surgery to replace it. Some things you can do to decrease possible damage are:

- avoid contact sports where you might be tackled
- take extra precautions when walking on ice to prevent slipping and falling

Pain

It is normal to have some pain in your penis and scrotum immediately after surgery and when you are first using the device. Approximately half of the patients in the 5-year clinical trial reported pain to their doctors after surgery.

WARNING: Contact your doctor if you have pain that is very severe or if it lasts longer than expected. Such pain my be a symptom of a medical condition or mechanical device malfunction.

Some patients have had chronic (continuing) pain with no known medical cause. These cases are not common but are unfortunate when they do happen. Sometimes these patients have chosen to have the device removed because the pain would not go away.

Migration

Migration is the movement of one or both cylinders, the pump, or reservoir within the body space where they were originally placed.

If migration occurs, it can cause pain, psychological/medical complications, or device malfunction. Migration may need to be corrected with surgery.

Causes of migration include:

- improperly-sized cylinders
- improper positioning of the MS pump or reservoir
- incorrect tubing length

Only 1% of the patients in the clinical trial had device parts which migrated.

WARNING: Contact your doctor if any part of the device is visible through your skin or if you cannot locate the MS pump in your scrotum.

Mechanical problems

Product wear (the use of the device over a period of time) or other mechanical problems may occur over time. Surgery may be required to correct the problem.

These problems may include unintentional (spontaneous, with no manipulation on your part) inflation or deflation of the device. Also included are difficulty or inability to inflate or deflate the device.

If such problems occur, first check the user instructions to be sure you are operating the device correctly. If you still have the same problem, contact your doctor.

About 10% of patients in the 5-year clinical trial experienced mechanical problems. The AMS 700 series with MS Pump has a new lock-out valve and Parylene coating design to reduce mechanical problems.

Edema

Edema is when the tissue next to any part of the device is swollen. It is normal for some swelling to occur in the healing period after surgery. About 1/3 of the patients in the clinical trial reported having swelling.

Bruising or discoloration of the penis

It is normal to have some bruising after surgery. About 10% of the patients in the clinical trial reported bruising to their doctors. In these patients, the bruising normally went away in about 13 days.

Obvious redness in penis or scrotum

It is normal to have some redness of the skin around the implant. However, extreme redness should be reported to your doctor. In the clinical trial, less than 5% of the patients reported obvious redness to their doctors. The redness went away in an average of 43 days.

Other

Problems which occurred in less than 4% of patients in the clinical trial were: problems with passing urine, painful joints, decreased penile sensation, hematoma, ejaculation problems, curving of the penis, problems with the surgical incision, numbness, tingling, pain in canal in penis which urine flows through, and pain or burning when urinating.

The following "Other" adverse device effects each occurred in 1.0% or fewer of the patients in the 5-year trial: inability to urinate,weakness, device parts "sticking" to the tissue inside the penis or scrotum, fever, dizziness, incorrect positioning of the device, depression (feeling of sadness or hopelessness), cellulitis (swelling and infection far below skin surface), fibrosis (the formation of fiber-like tissue around parts of the device), hematuria (blood in the urine), necrosis (death of body cells, tissue or skin), abnormal sexual function, urinary frequency (having to urinate a lot), infection in the bladder or canal which urine flows through), changes in the tip of the penis, thickening of the skin, stool (bowel movement) leakage, rheumatoid arthritis (swelling of muscles or tendons around joints), dry mouth, memory problems, baldness, diabetes, eye problems, headaches, vertigo, pelvic and back pain, kidney problems, urinary urgency (feeling of severe need to urinate often), reactions to sunlight and epigastric pain ("heartburn" related pain).

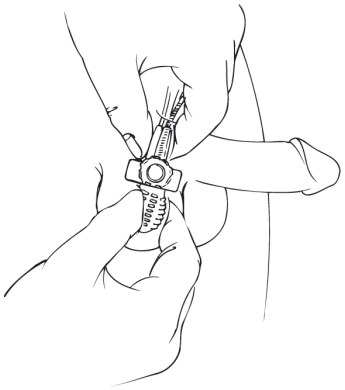
Please ask your doctor for explanation on any of the problems that you do not understand.

NOTE: All complication rates provided in this section are based on a prior version of the AMS inflatable penile prosthesis. Based on design similarities between the AMS 700 with MS Pump and this prior version, it is expected that the complication rates will be comparable.

9 Operating instructions.

9.1 Inflation

When you squeeze and release the pump bulb, the fluid moves from the reservoir, through the pump and into the cylinders. When the cylinders fill with fluid, the penis becomes erect.

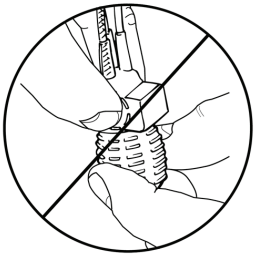


1. Feel for the pump in your scrotum.

2. Grasp the tubing above the deflation block with one hand to hold the pump in place.

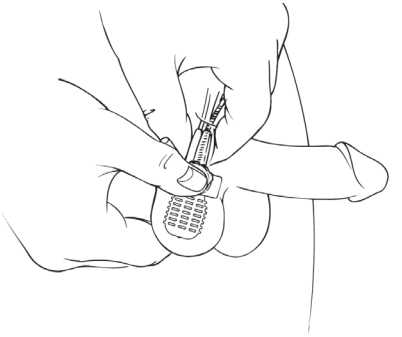
3. Use the thumb and forefinger of your other hand to locate the soft, rounded pump bulb.

4. Initially, squeeze the pump bulb **quickly** and **firmly**, and then release it to activate the pump. The remaining pump bulb squeezes can be slower. Releasing the pump bulb allows it to refill with fluid. Continue to alternate squeezing and releasing until the cylinders fill with fluid and become erect. Full erection may take as few as 10, or as many as 25 squeezes of the pump bulb.
   NOTE: Do not squeeze the deflation button while squeezing the pump bulb.



9.2 Deflation

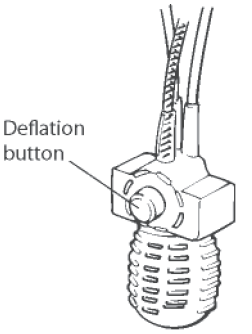
When you squeeze the deflation button for about four seconds the fluid begins to leave the cylinders and return to the reservoir. After about four seconds release the deflation button and the cylinders will return to their deflated position. The penis becomes soft.



1. Feel for the pump in your scrotum.

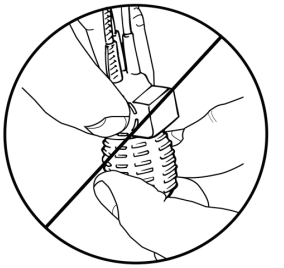
2. Grasp the tubing above the deflation block with one hand to hold the pump in place.

3. With your other hand, locate the raised deflation button on the deflation block.



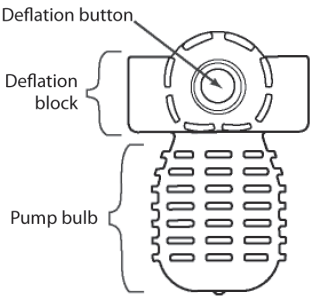
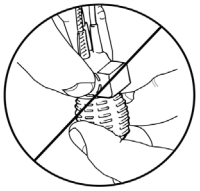
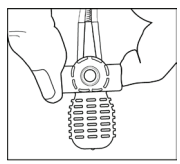
4. To effectively squeeze the deflation button, you must place a thumb and forefinger on opposite sides of the deflation block.

5. Squeeze the deflation button for about four seconds and then release. The cylinders will continue to deflate and the penis will become soft (flaccid).
   NOTE: Do not squeeze the deflation button while squeezing the pump bulb.



6. After cylinders have deflated, you may squeeze your penis to make it more flaccid.

10 Troubleshooting

Signs and Symptoms That May Develop After Surgery		
Symptom	**Problem**	**What to do***
Inability to inflate.   ***NOTE: Do not squeeze the deflation button while squeezing the pump bulb.***	Deflation button squeezed while squeezing the pump bulb.	1. Grasp the tubing above the deflation block with one hand to hold the pump in place. **2. Do not squeeze the deflation button while squeezing the pump bulb.** 3. Inflate normally.
	Pump bulb does not refill and is dimpled or collapsed.	1. Squeeze the deflation button. The pump bulb should refill. 2. First squeeze of the pump bulb should be quick and firm to activate the pump, then release. **3. Do not squeeze the deflation button while squeezing the pump bulb.** 4. Continue to squeeze and release normally to inflate cylinders.
	First pump bulb squeeze was not firm enough or long enough to activate pump bulb.	1. Firmly squeeze the deflation button. 2. First squeeze of the pump bulb should be quick and firm to activate the pump, then release. **3. Do not squeeze the deflation button while squeezing the pump bulb.** 4. Continue to squeeze and release normally to inflate cylinders.
	Possible mechanical problem.	Contact your doctor.
Inability to deflate.	Difficultly locating the deflation button.	1. Grasp the tubing above the deflation block with one hand to hold the pump in place. 2. With your other hand, locate the raised deflation button on the deflation block.
	Cylinders stay inflated after deflation button is squeezed and released.	Squeeze the deflation button for a longer time (at least 5 seconds).
	Deflation button and pump bulb were squeezed at the same time.	1. Squeeze the sides of deflation block for about 4 seconds, then release.  Squeezing the sides of the deflation block 2. Next, squeeze the deflation button for at least 5 seconds, then release. 3. Cylinders should deflate normally.
	Possible mechanical problem.	Contact your doctor.

Troubleshooting (continued)

Signs and Symptoms That May Develop After Surgery		
Symptom	**Problem**	**What to do***
Pain. Discharge from incision. Redness, swelling.	Infection.	Contact your doctor.
Cylinder surface can be seen through the skin.	Erosion of cylinders (associated with infection).	Contact your doctor.
Stomach Pain.	Erosion of pump (associated with infection).	Contact your doctor.
Pain.	Post-operative surgical pain.	Contact your doctor.
	Pain with intercourse.	Contact your doctor.
Insufficient flaccidity.	Cylinders stay partially inflated after deflation button is pressed and released.	Squeeze the deflation button for a longer period of time.
	Fluid remaining in cylinders.	Squeeze penis to make more flaccid.
Unintentional inflation.	Fluid has moved into cylinders.	Follow deflation instructions on page 30.
	Possible mechanical problem.	Contact your doctor.
Unintentional deflation or loss of rigidity.	Cylinders have not been fully inflated.	Follow inflation instructions on page 29.
	Deflation button was unintentionally squeezed.	Follow inflation instructions on page 29.
	Possible mechanical problem.	Contact your doctor.
Penile curving or bulging.	Possible mechanical problem.	Contact your doctor.
Inability to locate pump.	Pump has moved.	Contact your doctor.
Any part of the device is visible through your skin.	Possible mechanical problem.	Contact your doctor.
Pain, skin disruption (opening), leaking of body fluids, bruising.	Trauma.	Contact your doctor.
Skin rash or hives.	Possible allergic reaction.	Contact your doctor.
Difficulty breathing.	Possible allergic reaction.	Contact your doctor.

*For further assistance in operating your device call the AMS patient liaison at +1 952-930-6261, or 1-800-328-3881, extension 6261, or visit our Web site at www.AmericanMedicalSystems.com.

11. Summary

This summary is not meant to replace the complete instructions found in this manual. The entire manual should be read before operating your device.

Your inflatable penile prosthesis requires some manual dexterity to inflate and deflate.

The possibility of leakage, blockage, or device malfunction exists. Discuss any changes you notice in the function of your prosthesis with your doctor.

Contact your doctor immediately if there is:

- redness
- swelling
- heat around the incision area or drainage from the incision (symptoms of erosion)
- if your pain is very severe or lasts longer than expected
- if any part of your device is visible through your skin or
- if you cannot locate the MS pump in your scrotum

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Silicone elastomer safety	[Section 1.1]

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1004118 (P/N)
230006-01 (A/W Rev E) en